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POSTSCRIPTS

IN THIS ISSUE:

Official publication of the American Medical Writers Association Pacific Southwest Chapter

Postscripts
April 2016
AMWA Pacific Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and, book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

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ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers, editors and communicators may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact the Editor.

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April 2016 | Volume 6, No.42

In this issue. . .

COVER:
This month's cover remembers and honors the victims of last month's terrorist attack in Brussels; and sends Tintin, the Belgian reporter and adventurer, along with Snowy and Captain Haddock on a mission to foil bad guys and befriend people all over the world.
"Tintin mural." By Sinan Yüzakli. 2007. Located at Rue de l'Etuve 1000 Brussels, Belgium (www.tintin.com/en/). Source: https://www.flickr.com/photos/sinanyuzakli/4403665177 or https://flic.kr/p/7H8WeF. Permissions: CC BY-NC-ND 2.0

From the President's Desk

Hope you are enjoying spring in California. If you would like to get out a bit from your desk and network in a casual atmosphere with other chapter members, we would like to suggest that you consider sponsoring a chapter happy hour in your neighborhood or area. It's very easy to do–if you have a favorite restaurant or bar in your area that can accommodate a small or medium group, you pick a date, contact our outreach coordinator about a month ahead of time, and she sends out an email notice to the membership. You could also consider a different type of casual event, such as a brunch or group hike. If you would like to volunteer for your chapter in this way, please send an email to president@amwa-pacsw.org.

Our writers have been busy in the previous weeks and our April issue is full of excellent articles to distract you from your work. It begins with Rebecca Anderson's article and map of distinctive causes of death in the fifty states, followed by Hope Lafferty on how practice improves editing skills. Brea Midthune provides in-depth coverage of the recent meeting of The International Publication Planning Association (TIPPA) at Coronado, and Mary Ann Clifft and Clare Prendergast explain how to use journal finder software to find the perfect home for your manuscript. Dikran Toroser describes the close and complicated relationship between transparency and confidentiality in medical publications, and Kokil Tandon provides her recurring column on FDA news and updates. Teresa Gallagher reports on the recent meeting of the San Diego Clinical Research Association (SDCRN) that discussed reform of the clinical research industry through better use of technology and enhancing protocol quality. Noelle Demas and I provide coverage of two recent chapter events – she reports on a panel discussion at UCSD on medical writing as a career, and I report on a career transitions presentation in San Diego.

Finally, a reminder that it is almost time for the AMWA Pacific Coast Conference, planned by the Northern California chapter as a one-day event at the Park Central Hotel in San Francisco (in the vibrant South of Market district) on April 16. Registration information and descriptions of the workshops and presentations can be found at http://www.amwancal.org/events/index.html. The program includes two credit workshops and five open sessions, and topics include regulatory publishing, the Public Library of Science (PLOS), data transparency, LinkedIn, and Investigational New Drug (IND) Applications. We look forward to seeing you there!

Susan

Susan Vintilla-Friedman, MWC
President, AMWA Pacific Southwest Chapter

Focus on Pubs

If spring was the season of spectator sports of the publication world, the NCAA (Final Four) of medical communication would be two meetings: TIPPA 2016 which was held last month in San Diego and the upcoming ISMPP meeting at the other bookend of US, National Harbor (Maryland).

This is the season of pubs (publication) planning and development.

Mary Ann Clifft and Clare Prendergast write in this issue of *Postscripts*, "The ultimate goals of publishing research discoveries are to disseminate your findings to the biggest and most receptive audience and to do so in a cost-effective manner." But there is a larger goal too. We want to publish clinical trials and research data to help physicians, patients and policy makers make informed decisions. Besides professional and moral obligations to publish, there are also regulatory and legal imperative to comply with transparency initiatives. As expected, a peer-reviewed publication starts its journey in the guts of a clinical study protocol submitted to FDA and broadcasted on the clinicaltrials.gov (or other databases). A six-page summary of the TIPPA 2016 meeting by Brea Midthune on page 49 captures the complete publication development landscape.

The cradle-to-publication journey of the barge of clinical trials data from TFLs to a research article passes through several locks: authorship selection (GPP3), access to data, manuscript drafting process, selection of journal (see page 55), disclosures and conflict of interest reporting (Sunshine Act, ICMJE, etc) and confidentiality (company's non-disclosure agreements and in the journal's editorial office; see Dikran's article on page 57). Each "lock" has its own challenges, often understood well by the experts in the field, including publication planning professionals and CMPP-certified medical writers.

For medical writers wearing stripes other than publication development, the glow of pubs often creeps into their offices. It is unavoidable but should be welcomed because it is akin to learning a new language for the benefit of our brain's bookrack, just

as Amatera, a Financial Times (FT) reader, who responding to Jeremy Paxman's article (Voilà, English wins the battle of global tongues)[1], wrote this rebuttal in the online article's comment section:

> "Learning French or any other language is actually very useful, as it keeps your brain healthy, opens your mind and reduces the chances of criticizing things you don't know about. Medical studies have shown time and again that speaking other languages is beneficial for Alzheimers [sic] cases and generally improves brain functions. It also opens door to cultural subtleties."

So, in this spirit, Rebecca Anderson's column (which she calls Brain Candy) is one that I eagerly await every month. This month, she presents data from CDC with a color-coded map showing most distinctive causes of death in different States of the Union: "hyperplasia of prostate" in California, "discharge of firearms" in Arizona and "legal interventions" in Nevada paint an interesting story of our Chapter's quilt — our chapter is truly diverse in geography and death but held together by AMWA membership. . .*huh*!

Finally, nothing can really help the writing muscle unless there is practice, or "Praxis" — that's the name of a new column by Hope Lafferty, starting this month (see page 47). As Hope said, it takes not practice, but "perfect practice" to become a good writer and editor.

— Ajay Malik, PhD

ISMPP: International Society for Medical Publication Professionals; NCAA: National Collegiate Athletic Association; TIPPA: The International Publication Planning Association; TFLs: Tables, Figures and Listings.

[1]Paxman J. Voila, English wins the battle of global tongues. Financial Times. Apr 07, 2016. Available at: http://www.ft.com/cms/s/0/6a9c9872bae211e5b1518e15c9a029fb.html

The Infographics of Death

By Rebecca J. Anderson, PhD, AMWA Pacific Southwest Chapter Member

In case you missed it, the CDC has published a color-coded map showing the most distinctive cause of death in each state. The authors analyzed data from the first decade of this century according to the 136 causes of death classified by ICD-10. Using a fancy formula, they determined each state's most prevalent cause of death—in each case, it was at least double the corresponding national death rate for that cause.

The death map authors found that some of the 50 states (and DC) shared the same "distinctive" cause. But it was still a fairly long list of 23 unique causes, and plotting them on the map took just about all the hues on the color wheel.

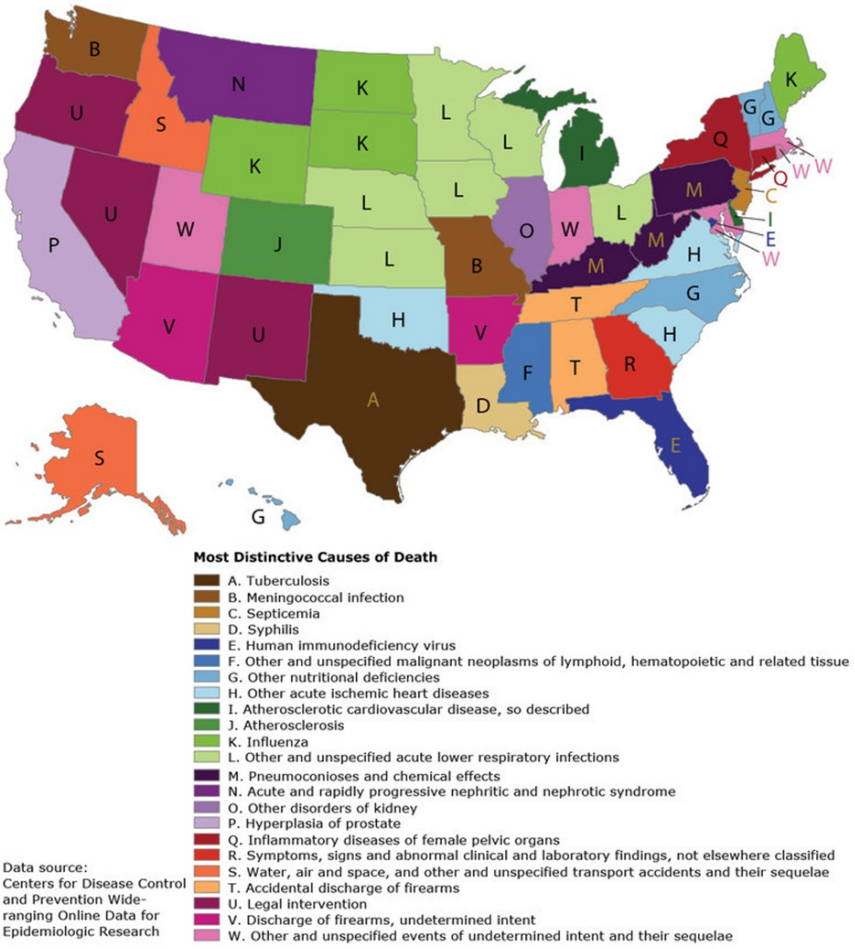
The lead author, Francis Boscoe, says he got the idea from a map showing the most popular musical artists, based on the online listening habits of people, state-by-state. The death map sings a different tune, of course.

No surprise that influenza and other lower respiratory infections were most popular in many northern states. Likewise, black lung topped the chart in the coal mining states of West Virginia, Pennsylvania, and Kentucky. And "air and water accidents" were the greatest "hits" in the outdoorsy states of Alaska and Idaho.

Also, it's logical, perhaps, that death by "legal intervention" and discharge of firearms in general beat all other causes in states where advocates of the 2nd Amendment and sovereign citizenship abound: Tennessee, Alabama, Arkansas, Arizona, New Mexico, Nevada, and Oregon.

However, missing from that list of country-and-western favorites was Texas, where tuberculosis apparently kills more people than anything else (and anywhere else). The fact that an easily preventable and treatable infectious disease surpassed the Lone Star State's legendary lethal injections and pistol-packer targets speaks volumes about its healthcare system (or more properly, the lack thereof).

Of course, Californians shouldn't pass judgment, considering the Golden State's winner, "hyperplasia of prostate." Whether that's a nod to Hollywood, Silicon Valley, or the state's legislators, I don't know. But we do have a lot of guys with big kahunas on the west coast.



By contrast, New York weighs in with "inflammatory diseases of female pelvic organs." I can't explain that, either. But certainly, the Empire State gave the world some very strong women: Nellie Bly, Leona Helmsley, Billie Holiday, Dorothy Parker, Eleanor Roosevelt, Margaret Sanger, Gloria Vanderbilt, Bella Abzug, and of course, Lady Liberty herself.

New York and California "book-end" the US on the east and west coasts, and they have a lot in common. But, the map suggests there's also some hanky-panky going on that we don't hear much about.

This type of speculation only serves to confirm Boscoe's rationale for presenting the data in a 21st century, infographic-like format. Even before the map was published, he says, it was a "robust conversation starter" amongst his CDC colleagues, and the online report quickly went viral. According to Boscoe, "It obviously works better than sending out a 16-page report that no one would open."

The CDC report can be found at: http://www.cdc.gov/pcd/issues/2015/14_0395.htm

See page 64 for author's biosketch

Praxis

By Hope J Lafferty, AM, ELS, AMWA Southeast Chapter Member

Practice Makes Perfect

After one of my recent seminars, I had this engaging conversation with a writer who wanted to develop her editing skills. She asked me if it just takes practice to become a good editor.

I was thrown back to high school and reminded of my band teacher's favorite instructions: "Go to the woodshed" (that is, "practice, practice, practice") and "It's not practice that makes perfect; it's perfect practice that makes perfect." Anyone that has gotten good at anything knows that you can spend all the time in the woodshed that you want, but you won't improve if you half-ass your practice.

In my first job as a medical editor, I learned this lesson anew. I had worked as a science editor for about 5 years on and off and had what I considered a decent amount of general editorial experience even before then. My new boss gave me a fairly short editing assignment, which I completed in a couple of hours.

After 10 minutes of review, she came back to me with an unmarked printout and asked me to give it another round. Dig in a little deeper. She had a nice way about her, but I felt annoyed. I thought I gave it a good edit already. But I was a new hire, and I probably treaded more lightly than I needed to. I edited the piece again, allowing myself to be more rigorous and creative with my edits.

After she reviewed my second round of edits, my boss came back with the unmarked printout and Mimi Zeiger's book *Essentials of Writing Biomedical Research Papers*. "Read the first few chapters and give this piece another edit," she instructed in her kind way. I thought to myself, "This is ridiculous, but she's the boss. If she wants me to spend so much time on such as short assignment, that's her call."
And then I read the book.

Let's just say that a lot of lights went on that afternoon and I felt like I had a new set of tools. I approached the editing assignment that third time with renewed confidence and skill that I didn't know I lacked hours earlier. I went with what I knew, but what I knew wasn't perfect for this assignment. It wasn't wrong, but it was incomplete. I needed to go to the woodshed.

I'm curious about how you have improved your editing skills (or writing skills) and if you have any resources that you would like to share. I'm always looking for answers to questions I have yet to formulate. Thanks for your suggestions.

HOPE J LAFFERTY, AM, ELS, has run her writing and training consultancy, Hope Lafferty Communications, since 2009. Over her career, she has worked as a writer in radio, high tech, engineering, instructional design, and medical research. Hope completed certificates in medical writing and editing from AMWA and the University of Chicago and in training from the Association for Talent Development. She serves as AMWA Annual Conference Chair-Elect and President-Elect of the Board of Editors in the Life Sciences (BELS). When she's not webcasting, podcasting, or otherwise modeling good writing practice, she takes road trips with her musician husband and comedian dog. Connect with Hope at hope@hopelafferty.com.

TIPPA 2016 Meeting Report*

By Brea Midthune, PhD, Secretary, AMWA Pacific Southwest Chapter Member

On February 29th 2016, the 15th Annual International Publication Planning Association (TIPPA) meeting convened in San Diego, CA for two days to discuss the evolving challenges impacting on the publications community. The meeting had approximately 100 attendees, including delegates, speakers, and sponsors. A summary of meeting is provided below.

Day 1: Monday 29th February 2016

Implementing the new GPP3 guidelines

The meeting opened with a topical discussion on the Good Publication Practice 3 (GPP3) guidelines, published in August 2015 by the International Society of Medical Publishing Professionals (ISMPP). Donna Simcoe (Medical Publications Consultant, Simcoe Consultants, Inc.) began the session by giving a brief overview of the history of the Good Publication Practice (GPP) guidelines which were originally published in 2003 and updated in 2009 (GPP2). She explained that GPP publications are intended to provide guidance on how to "responsibly and ethically develop and publish manuscripts sponsored by pharmaceutical companies". The newest publication, GPP3, offers additional guidance on interpreting International Committee of Medical Journal Editors (ICMJE) authorship criteria and improved clarity on section 6002 of the Affordable Care Actmore widely known as the Sunshine Act. Currently, there are a number of supporting materials to aid in the interpretation of GPP3 on the ISMPP website and there are plans to develop additional training materials.

Dikran Toroser (Medical Writing Senior Manager, Amgen) went on to discuss authorship criteria and author number. He noted that while there are a number of resources offering guidance for authorship, including the ICMJE guidelines and AMA manual of style, GPP3 specifically clarifies the "grey" areas of the ICMJE authorship criteria. However, he mentioned that the guidelines for author number are less clear and vary by resource; GPP3 recommends capping the author number at 10, however ICMJE is more flexible. Ensuing discussions revealed that many publication professionals agree that limiting the number of authors is not as important as following ICMJE criteria for authorship. This was echoed by the third panelist Monica Ramchandani (Global Biosimilars Development, Amgen) who noted that while Amgen does strive to follow the majority of the GPP3 guidelines, they prefer to be more flexible with author number, as outlined by the ICMJE guidelines. She also stated that Amgen disagrees with GPP3 on adding local presenters to encore bylines and instead follows ICMJE authorship guidelines. This point led to a lengthy discussion with the audience and while it was clear that views differed among the audience, most felt that significant author contribution was still the primary consideration.

Evolving best practices for working with authors – authorship and beyond

Chandra C. Abbott (Senior Manager, Scientific Communications, Sirtex Medical Ltd.) discussed best practices for forming and using publication steering committees, which is a group of authors and investigators whose ultimate goal is to help with the optimal dissemination of data on a product (usually from one or more clinical trials). In her experience, publication steering committees generally meet in-person and discuss topics such as publication ideas, identifying key audiences, and activity planning around manuscripts, key congresses and meetings. She emphasized the importance of meeting with the committee to enhance engagement and also recommended forming smaller working groups that convene periodically to discuss specific issues of interest (i.e. to help answer particular questions). For initial identification of the steering committee – as well as inviting principal investigators – the publication team may also take recommendations from experts in the field and from internal stakeholders.

Surendra Sharma (Global Medical Publications-Head, Alcon Laboratories, Inc.) covered good publication practices at Alcon. He stated that they strictly follow ICMJE guidelines for determining authorship. While they do not offer compensation for writing activities, they do offer medical writing editorial services. Additionally, while Alcon generally does not universally reimburse for conference attendance, there are exceptions, such as if the author had not planned to attend the conference where he/she is due to present. He stressed that

*Reprinted with permission from The Publication Plan (www.thepublicationplan.com), a website devoted to developments in the field of medical publications, medical writing and publication planning.

The Publication Plan is supported by Aspire Scientific (www.aspire-scientific.com). Aspire Scientific is a boutique medical writing and publication planning agency led by professionals with at least a decade of medical writing experience and supported by PhD and/or MSc educated writers and academics at the forefront of their specialist fields.

exceptions were all evaluated on a case-by-case basis and underlined the importance of making the attendance stipulations clear to authors. It was apparent that a similar approach was taken by most companies and this was a popular topic throughout the conference.

Don't be left behind – learn to evolve with the changing healthcare environment

Mike Smith (Managing Director, AlphaBioCom) spoke of the need for the pharmaceutical industry to evolve their communication strategies to include digital and social media to ensure greater dissemination of content. Though he acknowledged several barriers, such as regulations, lack of support in a conservative environment, and lack of media experts, he challenged the audience to think outside the box. For example, he suggested the inclusion of Quick Response (QR) codes on posters, which could link to an interactive poster presentation or to a poster with multiple language options. He also stressed the benefits of creating interactive communities on various platforms. To help with these strategies, he suggested that publications teams work closely with compliance teams to implement processes and procedures.

Publication planning department management in 2016 – one size does not fit all

This session was moderated by Welyn Bui (Executive Vice President, Scientific Communications, Meridius Health Communications). Panelists included Renu Juneja (Head of Medical Communications, MedImmune) and Surendra Sharma (Global Medical Publications Head, Alcon Laboratories, Inc.). Renu kicked off the session by discussing the evolving role of the medical writer. She estimated that only 60% of a medical writer's time is spent on scientific content, while the other 40% is spent on "processes". She stated that this is not a good use of time for MDs and PhDs and suggested the need for new roles to assist with publication management. These roles would be geared towards individuals who are detail-oriented and excel at following processes. She also noted that there is a move for more in-house writing teams and emphasized the benefit of having fully-integrated writers that are abreast of current conversations and strategy within the company. However, only about 25% of companies represented by the meeting attendees currently have in-house writers.

Renu and Surendra both contributed to a discussion centered on choosing the right journal for a publication. While impact factor and the top journal in a therapeutic area should still be considered, it was noted that other metrics are increasingly important, such as the ability to easily find the publication and to access it for free.

When asked where the publications teams will be in 3–5 years, Renu thought that publications teams would work more closely with corporate communications teams and that compliance issues would be less burdensome, allowing more time for scientific endeavors. She also hoped that time to publication would decrease to allow patients faster access to life-saving therapies. It was noted that most publishers have an option for rapid publication.

Clinical trial data transparency – data sharing and third party data inquiries

Debra Mayo (Vice President, Global Scientific Communications, Teva Pharmaceuticals) gave a very topical presentation on data transparency. She cited it as an opportunity to regain credibility with patients, but noted that there is still work to be done; currently only 57% of clinical trials are registered at clinicaltrials.gov, a US-based online registry. She encouraged publications teams to post data publicly, publish data in peer-reviewed journals, and provide public access to patient-level data. She also noted that several publishers now require public access to clinical trial data before they will consider publishing it.

In regards to data sharing, she encouraged companies to be proactive, indicating that sharing is not only a display of integrity, but is likely to improve patient outcomes. She stated that while there are disadvantages to data sharing, such as the release of ideas to competitors and impact on stock, data sharing will build trust, enhance patient care, offer new opportunities, and will ensure uniformity and equality.

Adapting to a more patient-centered approach to the scientific exchange

In this session, Richard White (Commercial Director, Oxford PharmaGenesis, Ltd.) discussed the need for the community to adopt a more patient-centered approach to publication practice. He encouraged the use of patient-reported outcomes (PRO) and emphasized that PROs are key to demonstrating healthcare value to stakeholders, such as payers, clinicians and regulators. He referenced studies that were successful in predicting clinical outcomes through PROs and went through the basic steps of developing generic- and disease-specific PRO instruments.

Mary Beth DeYoung (Global Publications Lead, AstraZeneca) then talked about the evolving role of the patient and the trend for increased patient involvement in the publication process. She mentioned that some journals, such as the British Medical Journal (BMJ), have implemented strategies to promote patient involvement and noted that there have been moves in the community to include patients in reviewing protocols, data interpretation and as authors on manuscripts. While concerns

were raised, she encouraged publication professionals to keep an open mind and consider that patients are increasingly savvy. To become more patient-centered, she stressed the importance of speaking “human”, publishing open access, obtaining patient feedback prior to submission, and the importance of thanking patients.

Operating on a global scale – streamlining global publication strategies

Jack Yeager (Chief Scientific Officer, Sylogent) discussed the difficulty of operating on a global scale, particularly in regards to communication between departments and the increasing pressure to know and understand all metadata. He stressed the importance of having a centralized data source to maintain data consistency across the company. He demonstrated this by sharing cases of companies that publicly shared conflicting data and the resulting negative impact.

Additionally, he noted that pharmaceutical and device companies have an increasing number of regulations, particularly those concerning data transparency, more processes, shorter timelines, smaller budgets, and fewer resources. While there were suggestions in previous discussions to “resource up”, he suggested that the better and more economic solution is to invest software to assist with theses challenges, such as those offered by Sylogent.

Publication strategies for rare disease and biosimilars

Robin LeWinter (Senior Director, Global Publications, Aegerion Pharmaceuticals) and Dheepa Chari (Director, US Scientific Communications, Novartis Pharmaceuticals Corporation) led the discussion on publication strategies for rare diseases by focusing on the unique challenges. Some of these challenges include the ease of identification of patients and the dearth of clinical trial data. They noted that often there is either no prior clinical data or data is from studies with a very small number of participants and no placebo.

Additionally, the patient journey is very convoluted and diagnosis and treatment guidelines often differ or are outdated, further complicating the understanding of the disease. Publishing clinical trials can be challenging because the trials are often small, single-arm studies with limited audience reach. Because of these challenges, Dheepa stressed the importance of outlining the value proposition of the drug in each publication.

Monica Ramchandani (Global Biosimilars Development, Amgen) followed this discussion by presenting on the challenges of publishing data on biosimilars. First, she explained that the regulatory pathway for biosimilars is inverted compared to innovator biologics with limited clinical evaluation which ultimately produces less data. With biosimilars, the majority of efforts are spent on structural and functional characterization, followed by non-clinical and clinical assessments. Typically, there is one phase I study to demonstrate the pharmacokinetics/pharmacodynamics and no phase II study. Additionally, usually one confirmatory clinical study in one indication is conducted to compare the biosimilar to the reference product with respect to efficacy, safety and immunogenicity.

She explained that publications for innovator biologics/drugs also have different medical objectives, which traditionally focus on clinical and health economics and outcomes research. However, the primary objective for biosimilars is to communicate similarity of the proposed biosimilar to the reference product with respect to structural/functional characterization and safety, potency, and purity. Additionally, it is necessary to communicate on policy issues such as labeling, as well as switching patients over from the reference drug, etc. She also noted that the type and extent of analysis done is sponsor-dependent and evaluation by regulatory agencies is done on a case-by-case basis; therefore, each biosimilar is unique and it is not possible to compare one biosimilar with another. All of these aspects present challenges in several areas, including educating internal and external stakeholders, sound study design and interpretation, and publishing in journals/congresses because of limited data and larger audience, which includes physicians and pharmacy directors, as well as scientists, payers, policy makers, regulators and other clinicians.

Photo by Ajay Malik

Day 2: Tuesday 1st March 2016

Journal editor perspective – trends in publishing for 2016 and beyond

This session was moderated by Lisa DeTora (Assistant Professor of Writing Studies, Hofstra University). Leslie Citrome (Editor-in-Chief, International Journal of Clinical Practice; Clinical Professor of Psychiatry and Behavioral Sciences, New York Medical College) started the discussion by listing top trends in publishing, which included the increasing use of open access, the evolution of metrics, and the disappearance of paper journals. Included in his discussion on metrics, was the increasing popularity of alternative metrics (including the altmetric score), which measure the attention a publication receives in the news, blogs, tweets, and other social media. (Altmetric scores can easily be obtained for any publication with a DOI through a free Altmetric plug-in.) He also suggested the audience view impact factors and other metrics with caution due to gaming techniques that overinflate the score. Rounding out his list were fraud control, experimentation with aspects of peer review and remuneration due to difficulty in finding reviewers, and more guidance for authors to help reduce editorial workload and make sure the "right" articles are published.

Alan Lyles (Henry A. Rosenberg Professor of Government, Business and Nonprofit Partnerships, University of Baltimore; Docent, Faculty of Pharmacy, University of Helsinki) continued the discussion and listed reproducibility, open peer review and patient peer review as top publishing trends. He also mentioned the expanded use of impact metrics, such as the altmetric score and scoring views and downloads. He noted that the inclusion of pharmacoeconomic information in publications is increasing, which is a challenge due to the dearth of reviewers. Similar to Leslie, he sees author assistance increasing. He also agreed that the flood of publications is a real issue for editors and encourages authors to use guidance for submissions. Within this discussion, he noted that a main reason why journals reject articles is due to a poorly written abstract and emphasized the need to provide context within the abstract.

The benefits and challenges of integrating health economics and outcomes research (HEOR) data into your publications

Susan Ryan (Medical Communications Strategic Director, InScience Communications) started this session by discussing the rise in HEOR publications, which is driven in part by the increasing role of payers in healthcare decision making. Data for HEOR publications is post-launch real-world evidence and can be extracted from a wealth of sources including electronic medical records, PROs, administrative claims, insurance claims data, national surveys, and patient registries.

She went on to state that adding HEOR modelling to the publication plan is important since it can identify cost drivers associated with a drug/therapy area, allow for comparison with competitors without the need for clinical trials, and offers more opportunities to communicate and publish. However, one current transparency issue with HEOR is that companies are not obligated to publish if the findings are not in their favor (i.e. final data may not be supportive of the desired message). Additionally, she noted that it is necessary to have at least 12 months of post-launch real-world data in order to have a robust study and emphasized the need to ask the "right questions" to get the "right answer". She finished her discussion indicating the need to define internal interpretations of publication guidelines, particularly if paying a consultant to perform the data analysis.

Dheepa Chari (Director, US Scientific Communications, Novartis Pharmaceuticals Corporation) continued the conversation by discussing her experience with integrating HEOR into publication plans. She noted that for the past couple years, the HEOR team and publications teams have been closely integrated. She described the importance of understanding what each team does and how this helped them to integrate HEOR publications into the overall plan up front. One question they are currently discussing is the best way to interpret their economic data from a medical perspective and discern whether there are more opportunities to utilize the information. She mentioned the idea of writing HEOR-based review articles, which may ultimately consolidate the information and present it in a more impactful way.

Case study: Authorship selection issues

Neil Matheson (Global Chief Executive Officer, Huntsworth Health) started off the session by asking the audience a number of questions regarding publication planning. It was discovered that 33% (the majority) felt that a publication steering committee should be formed as early as possible. Interestingly, however, most of the audience reported working with publication steering committees less than 50% of the time.

He then engaged the audience in discussion by walking through several difficult, real-world cases involving conflict in steering committees as well as authorship selection. He spoke of a steering committee that had conflicting views due to regional differences in medical practice. This committee also had different types of specialists, which added to the complexity of the discussion. He encouraged the audience to think about these issues during steering committee selection and if/when it is appropriate for the sponsor to step in to resolve these issues.

He followed this with examples of authors desiring

authorship or senior authorship positions without proper contributions and went on to describe a method developed by his team to help determine authorship rank. This method involves the scoring of several parameters including data analysis contribution, patient enrollment. He concluded by suggesting that if there is not clear guidance on a particular authorship situation, company policy and common sense should steer the decision. He also emphasized the importance of establishing clear authorship guidelines up front to help avoid these issues.

Two years of Sunshine – how are we doing?

Carolyn McAuliffe (Director, Medical Communications, Masimo Corporation) opened this session with a discussion surrounding the current requirement for manufacturers of pharmaceutical drugs and devices, as well as group purchasing organizations, to report any payments to US healthcare professionals (HCP) and teaching institutions. She went on to acknowledge that there are many different interpretations of HCP payments and transfer of value (TOV). Currently, there are several published guidelines to assist in interpretation of the Sunshine Act, such as those published by the International Society for Medical Publishing Professionals (ISMPP), Centers for Medicare and Medicaid Services (CMS), and the American Medical Association (AMA). However, Carolyn also suggested having discussions with company legal and compliance teams. She noted that it behooves the pharmaceutical industry to participate not only as an ethical commitment to the community but to ensure that clinical decision making is based on the patient's best interest.

Dikran Toroser (Medical Writing Senior Manager, Amgen) followed this up with a discussion on the Sunshine Act from a medical writer's perspective. He reported that relationships with US authors have not changed drastically, but emphasized the importance of informing authors upfront that there may be a TOV reported. He also said that it hasn't drastically changed the way they operate, but the extra processes involved can be time consuming to follow. Between 2015 and 2016 he has seen an improvement in processes, and noted that they no longer perform TOV calculations at the time of submission, but at the time of acceptance, which streamlines the process. He has also noticed that stakeholders and colleagues are increasingly knowledgeable about the Sunshine Act.

Marion Enie (Operational Excellence Lead, Envision Pharma) closed the session by reviewing a survey on reporting TOV trends that was performed by Envision. Through the survey, which included 28 companies of varying size, they determined that larger companies are more likely to report than smaller companies, though she acknowledged that reporting was still quite low, even for this group (~50%). They also found that the method of calculation and frequency of reporting varied greatly by company and were surprised to find that the presence of a corporate integrity agreement doesn't seem to affect the decision to report. When surveying the meeting audience, ~50% of the attendees indicated that their companies were reporting and discussions followed surrounding the risk/benefit of not reporting.

Publication contracting made simple

This session was chaired by Welyn Bui (Executive Vice President, Scientific Communications, Meridius Health Communications). George Samman (Director of Operations/Team Leader, Pfizer, Inc.) gave an account of his experience at Pfizer, where it took an average of 45 business days to fully execute a contract for medical writing services. This protracted

Photo by Ajay Malik

Members taking a break from the TIPPA meeting at the happy hour organized by AMWA Pacific Southwest Chapter.

system led him to look at alternative approaches, and he assessed systems already in place in their procurement department. He noted the financial benefit of building a system from software already owned by the company and led the audience through the development and implementation of their new contracting system on Decideware, which has reduced the time spent on contracts by 60%. Additionally, it allows users to easily track the contract and offers a formal repository for easy access. He ended the session by stressing the importance of surveying other departments within your company when trying to solve system issues.

Extending the reach of your publication through advanced technology

Next, Tim Collinson (Business Unit Head, West Coast, Fishawack Communications) spoke about alternative methods to extend the reach of publications. Within this topic he discussed the potential for interactive ebooks, supplemental video data, and extending the use of Quick Response (QR) codes to link to interactive material, such as videos of poster presentations.

He also discussed the value of engaging in social media, where the primary objectives should be to monitor activity, redirect to other relevant information, and converse with the audience. He also highlighted the additional benefit of being able to extract metrics from social media activities.

He named several issues holding the field back from embracing new technology, such as lack of support from legal/compliance, difficulty in measuring return on investment and a generational gap. However, he encouraged the audience to work through these issues.

Transparency in the clinical trial design – spotlight on the protocol

In the final session of the meeting, Lisa DeTora (Assistant Professor of Writing Studies, Hofstra University) spoke about transparency in clinical trial design and first described how clinical trial transparency emerged. She stated that in addition to high profile legal cases of "data hiding", the importance of transparency gained traction from several other factors, including the need for patients to find clinical trials, the call for greater access to data in order to generate more robust, systematic results from meta analyses, and from published guidelines calling for trial registration before publication (such as ICMJE).

She then discussed the difference between publication transparency and trial transparency. Publication transparency involves full disclosure of information such as the origin of the data, who conducted the trial and disclosures of monetary payment or intellectual ties. Trial transparency centers on what trials are being run, as well as their location, status, results, design, sponsor and payments. She noted the importance of transparency in clinical trials and advised the audience to be honest, offer information, and "not to wait to be asked".

Finally, she discussed the importance of protocols in transparency. She reminded the audience that there is a large list of directives on the topic, including ICHE6, the European Directive, and institutional guidelines. She also emphasized that the audience should remember that the primary goals are to build on known and established knowledge and to maintain ethical standards. She cautioned that innovation is not always desirable and that protocols should be standardized in order to offer valid comparisons between the studies and contribute to metadata. She also noted the importance of writing quality and suggested a free online training resource by Trish Groves at BMJ.

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Matchmaker, Matchmaker, Make Me a Match:
Using Journal Finders to Match Manuscripts with Suitable Journals

By Mary Ann Clifft, MS[1], and Clare Prendergast, MA[2]
[1]Barrow Neurological Institute and [2]Norton Thoracic Institute
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In an ideal world, you should have your target journal in mind before you ever sit down to write an article. You might be aiming at the top journal in your specialty or subspecialty, or you might be focusing on a journal with a high impact factor. You might be following the guidance of a mentor or coauthor, or you might be drawing inspiration from the sources of the published articles you find yourself reviewing and citing. Regardless of the approach, you're seeking the perfect home for your manuscript. But if your specialty is awash in journals (more than 5,600 journals are indexed in MEDLINE alone), how do you narrow down your choices to find the one most suitable for your manuscript?

The ultimate goals of publishing research discoveries are to disseminate your findings to the biggest and most receptive audience and to do so in a cost-effective manner. If your aim is off by even the slightest margin, you may end up submitting to an unsuitable journal that rejects your manuscript out of hand or sends it through endlessly unhelpful rounds of peer review. Your manuscript may wander aimlessly from journal to journal, collecting rejection notice after rejection notice. If it's accepted, it may languish in the "coming soon" pile. If it's published, it may go unnoticed by your far-flung counterparts because of the obscurity of the journal or the barrier of a high pay wall.

To mitigate these factors, you can strive to more clearly define your target. Some factors to consider when searching for the appropriate journal include knowing the topics on which it publishes (e.g., applied science, clinical research, basic research) and the types of articles it publishes, as well as their format and length. It's also helpful to know its readership (whether it is field-specific) and to be aware of its reputation (impact factor and prestige of its editors and the authors it publishes). Once you have narrowed down the possibilities, you should browse their websites, read a few sample articles similar in scope to yours, and review their instructions for authors—and be ready to follow them to the *Nth* degree. Note that a journal's instructions to authors should supersede any guideline set forth by the *AMA Manual of Style* or other style guides.

As you move through the process of distilling your research into a compelling story on paper, try to step back from your work and view it objectively: Are your topic and its presentation really suitable for *The Lancet* or the *New England Journal of Medicine*? Although aiming high is commendable in many ways, might there not be a quality niche journal where your manuscript would truly stand out?

Other aspects of a target journal to consider include its frequency of publication, its average time from acceptance to publication, and whether it publishes electronically before print—or just via Epub. To reach the broadest possible audience, you might only consider open access journals, provided that they are properly indexed in MEDLINE and other major databases, adhere to established ethical standards (no Retraction Watch appearances [http://retractionwatch.com/]), and do not charge fees so exorbitant they are deemed predatory (see Beall's List of Predatory Journals: https://scholarlyoa.com/publishers/).

Despite all this legwork, your choice might still not be clear-cut. If you're feeling utterly stymied, here's an entertaining—and possibly helpful—alternative: A **journal finder**. Several publishers have compiled free electronic databases to match your manuscript with the perfect journal—preferably one of theirs.

Elsevier's website states that it publishes over 2,500 peer-reviewed scientific, technical, and health journals spanning 24 major scientific disciplines. Its online **Journal Finder** software (http://journalfinder.elsevier.com/) searches among those journals to help find your manuscript a home. The Journal Finder website modestly proclaims that it identifies journals "that could be best suited for publishing your scientific article" by using "smart search technology and field-of-research specific vocabularies." This match-making occurs after you paste the title and abstract of your manuscript into the search fields and select "Find Journals." To optimize the search, you can select fields of research (e.g., Chemistry; Physics; Life and Health Sciences) or you can limit the search to open access journals. Within seconds, the Journal Finder produces a list of its top 10 recommended Elsevier journals (with links), along with their impact factors, editorial turnaround times, acceptance rates, production timelines, open access status plus full-length article fees, and embargo periods.

Another free (up to a point; beware that some services incur a fee) journal finder is **Edanz Editing's Journal Selector** (https://www.edanzediting.com/journal-selector). It claims to be capable of searching "over 28,000 journals and 7.5 million abstracts to find the journal that's right for you." You can conduct a general

search or a specific search by journal name, publisher, field of study, or abstract/keywords. For a general Edanz search, inputting your title and abstract and then selecting "GO" might pull up 500 results, whereas a specific abstract/keywords search might return only 15. The retrieved information for each journal includes journal title and description (with link), impact factor with year, and whether the journal is in the Science Citation Index Expanded (SCI-E). Take these suggestions with a grain of salt—there may be 28,000 journals indexed in Edanz, but only 5,600 are indexed in MEDLINE. Be sure to verify that any journal you choose to submit a manuscript to is reputable.

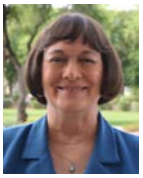
Other journal finders are the **JournalGuide** (https://www.journalguide.com) from Research Square, which boasts a database of 46,000 titles; the **Journal/Author Name Estimator (Jane)** (http://jane.biosemantics.org) from the BioSemantics Group in Rotterdam, which includes only those journals listed in MEDLINE, the database of the US National Library of Medicine; and the London-based **Cofactor Journal Selector** (http://cofactorscience.com/journal-selector), where you can set selection criteria to retrieve journal titles, with services free up to a point.

Just for the fun of it, take an article you've had published, and see where one or two of these journal finders would have sent you instead. But if you use them for future manuscripts, keep in mind that these tools, while handy, search only a limited cache of journals to find that dream home for your manuscript.

In an unusual twist on journal finders, some publishers of numerous journals, such as **BioMed Central: The Open Access Publisher**, are also beginning to offer "transfers." If there are two or three journals in their stable that might be a good fit for your manuscript, and your first choice rejects it, then you can ask for a transfer to another journal—your second or third choice—within the group. Transferring a manuscript usually avoids the hassle of having to upload all your manuscript files again for the new journal.

A search of Elsevier's Journal Finder using the article title and abstract of a high-profile stem-cell article retracted six months after publication in *Nature* (Obokata H. et al. Stimulus-triggered Fate Conversion of Somatic Cells Into Pluripotency. *Nature* 2014;505:641-64) identified *Stem Cell Reports* as the No. 1 target journal at Elsevier. If Obokata et al. had submitted there instead of to *Nature*, would the manipulated images and questionable findings in their report have been identified more quickly? For the same article, an Edanz Journal Selector search identified *Nature* as the seventh most suitable journal in its top-15 list of recommended journals. Higher-ranked specialty journals included *The Journal of Immunology*; *Histochemistry and Cell Biology*; and the *Journal of Biological Chemistry*. All three journals seem as suitable as *Nature*—if not more so—but publication in any of them might not have garnered the widespread publicity that ultimately led to the authors' downfall.

No matter how you decide to go about marrying your manuscript to the perfect journal, putting some forethought into it—and perhaps searching the universe of publications with a journal finder—should make the match-making go more smoothly.



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AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc., Thousand Oaks, Calif.

Ethics, Confidentiality, Transparency and Misconduct—a Complex Blend

Transparency is recognized as being crucial in increasing accountability in health care. It is fair to say that medical publications are undergoing a paradigm shift in terms of transparency requirements. Stringent disclosure requirements have been developed by universities, hospitals and medical journals to document potential conflicts of interest, and many voluntary codes of conduct have been adopted by industry organizations.

However, it is important to recognize that aspects of the publication process still require confidentiality. For example, Editors have a duty of confidentiality to authors. Editors are tasked with treating all submitted manuscripts as confidential documents, which means they will not divulge information about a manuscript to anyone without the authors' permission. The AMA manual of style provides important information regarding some of the historical basis for this essential confidentiality and the circumstances in which confidentiality must be maintained.

Confidentiality in typical journals. Journals such as *BMJ* take care to carefully list, upfront, the strictly limited number of people who may have access to a submitted manuscript[1]:

> —*"Editors and editorial staff, including medical students on placement and occasional overseas visitors - usually doctors or editors from other journals;*
> —*External reviewers, including statisticians and experts in trial methods;*
> —*Members of the journal's editorial committees, comprising the final stage in our peer review process for original research articles;*
> —*The only occasion when details about a manuscript might be passed to a third party without the authors' permission is if the editor suspects serious research misconduct."*

Confidentiality in Allegations of Scientific Misconduct. Allegations of scientific misconduct (eg, plagiarism) must be considered carefully within rules of confidentiality. In cases of credible allegations, however, an editor may need to disclose specific confidential information in a controlled manner. For example, after the credible allegation an editor may need to contact an author's institution to request a formal investigation. This can be done by a telephone call or a brief formal letter marked confidential. During such investigations, editors should avoid including details of such cases in e-mails that can be widely circulated and should avoid posting details.

Confidentiality in Legal Petitions and Claims for Privileged Information. A number of cases in US law have served as the foundation for or have directly supported the confidential nature of the editorial and peer review process. After the 1993 US Supreme Court ruling in *Daubert v Merrell Dow Pharmaceuticals Inc*, concerns arose that attempts to breach the confidential nature of the editorial process would increase through subpoenas for journal records. In 1994, a legal precedent was set regarding confidentiality and protection from attempts to invade the confidential and privileged nature of the editorial process[2]:

> In *Cukier v American Medical Association*, an author whose manuscript had been rejected by *JAMA* actually sued to compel the journal to disclose the identity of those persons responsible for allegedly defamatory statements made to the editors. Citing the confidential nature of the peer review process, the editors refused to disclose the information. The Courts ruled that the editors were not required to disclose this information because members of the news media (in this case, journal editors) cannot be compelled to disclose sources unless the information cannot be obtained elsewhere and such disclosure is essential to the protection of the public interest.

Confidentiality in Selecting Editors and Editorial Board Members. When editors or editorial board members are interviewed and evaluated for a prospective position with a journal, all participants in the selection process should be reminded that all discussions should remain confidential. In some cases, a signed statement of confidentiality may be requested of members of search/interview committees. Without assurance of such confidentiality, professional reputations and the journal's relationship with influential academic and political leaders may be jeopardized.

See pages 155 to 168 in the AMA Manual of Style 10th edition for additional information.

Acknowledgement: Thanks are due to Ajay Malik, PhD, for editorial input.

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See page 64 for author's biosketch

News and Updates from the FDA

Kokil Tandon, MBBS, MBA
Member, AMWA Pacific Southwest Chapter

During the last month, the agency granted approval to novel treatments for rare disease indications including Hemophilia B, an advanced form of non-small cell lung cancer (NSCLC) and inhalational anthrax.

Idelvion, Coagulation Factor IX (Recombinant), Albumin Fusion Protein
In early March, the FDA approved the first coagulation factor-albumin fusion protein product for use in Hemophilia B. This is a rare inherited bleeding disorder found to occur in children and adults. Idelvion (CSL Behring) is used to replace Factor IX, a naturally occurring clotting factor that is missing or defective in Hemophilia B patients. It is indicated for on-demand control and prevention of bleeding episodes, management of perioperative bleeding and as a prophylactic measure to reduce the frequency of bleeding episodes. Idelvion is produced by recombinant DNA technology and is modified to last longer in the blood.

Xalkori
Later in the month, the agency granted approval to the first treatment for a rare form of advanced NSCLC. Xalkori (Pfizer) is the only agency approved treatment for NSCLC patients whose tumors have an ROS-1 gene alteration. This alteration is present in approximately 1 percent of NSCLC patients and the consequent disease appears similar to NSCLC with anaplastic lymphoma kinase (ALK) gene alterations, for which Xalkori was approved previously. Xalkori blocks the activity of the ROS-1 protein in tumors which may prevent NSCLC from spreading/growing. The FDA granted breakthrough therapy designation, priority review status and orphan drug designation, to the expanded use application of Xalkori.

Anthim
Anthim (Elusys Therapeutics, Inc.) was approved for the treatment of inhalational anthrax, a rare disease, caused by breathing the spores of the bacterium Bacillus anthracis. Since these spores can be spread by release in the air and are resistant to being destroyed, Anthrax is considered a potential bioterrorism threat. Anthim is a monoclonal antibody that neutralizes toxins produced by this bacterium and was developed in collaboration with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority. It is indicated for disease treatment in combination with antibacterial drugs, as well as for disease prevention when alternative therapies are unavailable or inappropriate. Anthim was approved under the FDA's Animal Rule, which enables the use of efficacy findings from animal studies to substantiate approval, when efficacy trials in humans are not feasible or ethical to conduct.

Voluntary recalls were issued by Sagent Pharmaceuticals, Inc., Teva Pharmaceuticals and Hospira, Inc.

A few advisory committee meetings, as well as several other events have been scheduled for April, as detailed below.

Selected FDA Announcements

Date	Announcement
02-26-16	A federal judge entered a consent decree of permanent injunction between the United States and James R. Hill, a Florida dietary supplement distributor doing business as Viruxo LLC. The action was brought by the U.S. Department of Justice, on behalf of the FDA. According to the complaint filed with the decree, Hill unlawfully distributed an unapproved new drug and misbranded drug. The complaint includes a civil fraud charge for his intent to defraud consumers by promoting the product as a cure for herpes. The decree prohibits Hill from marketing misbranded or unapproved new drugs. Before he is allowed to restart operations, he must hire a labeling expert, remove all representations from his website and other promotional materials that his product can cure, mitigate, treat, or prevent disease, and receive written permission from the agency to resume operations. Also, Hill has to notify the FDA at least 14 days before the creation of a new website, or link or reference to another website, which conveys information about his products.[1]
03-01-16	Sagent Pharmaceuticals, Inc. initiated a voluntary nationwide recall of one lot of Fluconazole Injection, USP, (in 0.9% Sodium Chloride) 200mg per 100mL flexible container bag, Lot 40608 manufactured by ACS Dobfar INFO S.A. and distributed by Sagent. This recall was issued due to an out of specification impurity result detected during routine quality testing of stability samples at the 18-month interval. This impurity has been identified as Metronidazole, which may decrease product effectiveness or may lead to an increase in the dose of Metronidazole received by patients taking concomitant Metronidazole medication.[2]

03-09-16	Teva Pharmaceuticals announced a voluntary nationwide recall of one lot of amikacin sulfate injection USP (Lot #4750915), 1 gram/4mL (250 mg/mL) vials. The recall was issued due to the potential presence of particulate matter identified as glass in one vial. Administration of a glass particulate, may cause local irritation or swelling or other serious and life-threatening outcomes.[3]
03-18-16	Hospira, Inc., announced a voluntary recall of one lot of 8.4% Sodium Bicarbonate Injection, USP (Lot 56-148-EV) at the hospital/retail level due to the presence of a particulate within a single–dose glass fliptop vial. The presence of the particulate could lead to local/systemic ill effects.[4]
03-22-16	As part of its ongoing efforts to educate prescribers and patients about potential risks of opioid use, the agency announced class-wide safety labeling changes for immediate-release opioid pain medications. This includes the requirement of a new boxed warning that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening if not diagnosed/treated per neonatology protocols. The FDA also announced updated labeling requirements for all prescription opioid products, to include safety information about potentially harmful drug interactions with other medicines, opioid effects on the endocrine system, and associated serious disorders.[5]
03-24-16	The FDA issued a draft guidance to promote the development of generic versions of approved opioids with abuse-deterrent formulations. This guidance included recommendations about the studies that should be conducted to demonstrate that a generic opioid is no less abuse-deterrent than the brand name product, with respect to all potential routes of abuse. In order to solicit feedback on the guidance as from external experts and the public, it is planned that the agency will organize a public meeting later in the year The meeting's agenda will also include the discussion of a wide variety of topics pertaining to the use of abuse-deterrent technology to reduce prescription opioid abuse. These efforts are part of the FDA's overall approach to reverse the opioid abuse epidemic, while facilitating patients' access to effective pain medication.[6]

Selected FDA Approvals

Drug	Indication	Company
Briviact®	Add-on treatment for partial onset seizures in epileptic patients aged 16 years and older[7]	UCB, Inc.
Taltz®	Moderate-to-severe plaque psoriasis[8]	Eli Lilly and Company
Cinqair®	Maintenance treatment of severe asthma in patients aged 18 years and older, along with other asthma medicines[9]	Teva Pharmaceuticals

April 2016 Advisory Committee Meetings

Date	Committee
04/07/16	Meeting of the Gastrointestinal Drugs Advisory Committee Meeting Announcement – Discussion of the NDA submitted by Intercept Pharmaceuticals, Inc.[10]
04/12/16	Oncologic Drugs Advisory Committee Meeting Announcement – Discussion of the NDA submitted by Clovis Oncology, Inc.[11]
04/15/16	Meeting of the Nonprescription Drugs Advisory Committee Meeting Announcement – Discussion of data submitted by Galderma Laboratories, L.P. to support supplemental NDA.[12]
04/25/16	Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee – Discussion of NDA sponsored by Sarepta Therapeutics, Inc.[13]

April 2016 Conferences, Workshops and Public Meetings

Date	Title
04/13-14/16	FDA Small Business Regulatory Education for Industry: Generic Drugs Forum 2016.[14]
04/14-15/16	Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification Workshop.[15]

04/18-20/16	AAPS/ITC Joint Workshop on Drug Transporters in ADME.[16]
04/20/16	The FDA CDER & ASCPT Annual William B. Abrams Memorial Lectureship.[17]
04/22/16	Childhood Cancer Advocacy Forum 2016.[18]
04/25/16	Seventh Annual Predictive Safety Testing Consortium (PSTC) / FDA CDER Scientific Workshop.[19]
04/25-27/16	The 10th Annual FDA/DIA Statistics Forum 2016.[20]
04/26/16	Workshop on Clinical Outcome Assessments (COAs) in Cancer Clinical Trials.[21]
04/27-28/16	Evaluation of the Safety of Drugs and Biological Products used during Lactation.[22]

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm
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- For information on drugs to be discontinued, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
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Technology and Standardization Are Key to Reform of Clinical Research Industry

Teresa Gallagher, PhD, MPH

President, San Diego Clinical Research Network

San Diego Clinical Research Network (SDCRN) recently hosted Laurie Halloran, President and CEO of Halloran Consulting Group in Boston, who spoke on March 2 at the Sanford Consortium for Regenerative Medicine on trends in clinical research – "The Big Picture, What is Here, What is Coming and How Will We Lead Through It?" Laurie Halloran, BSN, MS, is the founder of Halloran Consulting Group (www.hallorancg.com), and is recognized as an industry expert in improving the organizational effectiveness of clinical research programs.

In 2016, the "Big Picture" clinical research trends include impending changes to the Common Rule, patient centricity, and ongoing attempts to decrease inefficiencies in clinical trials. The Common Rule is a rule of ethics regarding research involving human subjects in the U.S. – some of the major changes being proposed are the rules relating to informed consent, which would be significantly tightened. Patient centricity involves designing protocols with patients in mind and incorporating modern technologies to ease the patient's journey through the clinical trial.

The clinical research challenges today are not that different than they have been, but the alternatives for organizations are new, including addressing the issue of increasing protocol complexity, adopting cloud-based technology to increase efficiency, and leveraging study testing in patients' homes to decrease costs.

Two major initiatives with high potential to transform the clinical research enterprise are technology and standardization. The digital or "site-less" clinical trial is "tantalizing, yet probably still off in the distance," while improving protocol quality is "here and now."

Protocol quality can be improved by designing more patient-centric trials and using companion diagnostics to strengthen the patient population and endpoints.

We have new opportunities to enhance the participation of research sites and investigators, and novel initiatives are underway to address inefficiencies at the study site level. Engaging with patients through direct-to-patient digital marketing and working with advocacy associations will help study recruitment. Data Revolution, spurred by a massive drop in the cost of sequencing genomes in the last ten years and the increased speed of data processing, has led to the collection and availability of a variety and volume of data from diverse healthcare and life science sources. We will need to manage all this data and apply standards that are common across all systems.

How can we prepare for this future? Halloran recommends that having a crystal clear focus on your organization's needs and goals; facilitating all the technology efficiency you can manage; and being prepared for intense pressure on development timelines in a highly competitive environment for talent are all key ingredients for favorable outcomes for life science organizations.

TERESA GALLAGHER, PhD, MPH is the President and Founder of San Diego Clinical Research Network (SDCRN). SDCRN has an active LinkedIn discussion group. SDCRN also publishes *Clinical Currents*, a free, bi-weekly clinical research newsletter, and produces webinars on clinical research topics. SDCRN events and webinars are available through The Clinical Research Connection (TCRC), an online resource on developments in clinical research, which is available at http://theclinicalresearchconnection.com/
To subscribe to *Clinical Currents*, go to http://eepurl.com/bQvCyD. Teresa can be reached at tcgallagherr@gmail.com

Medical Writing as a Career; Panel Discussion at UCSD Career Services Center

Noelle H Demas, MS

Past President, AMWA Pacific Southwest Chapter (2009-2011)

On February 22, 2016, in collaboration with the Career Services Center at the University of California, San Diego (UCSD), our AMWA Pacific Southwest chapter Outreach Coordinator, Asoka Banno, organized a panel discussion to present medical writing as a career. Approximately 14 postdoctoral fellows and graduate students from UCSD attended the event. Two chapter members, Amy Lindsay and I volunteered to participate as panelists.

The session started off with a timely introduction to the newly launched UCSD Medical Writing Certificate program by Leslie Bruce, Director of Healthcare Leadership and Community Outreach; followed by a brief and informative introduction to AMWA from our AMWA Pacific Southwest Chapter President, Susan Vintilla-Friedman. The UCSD host then introduced Amy and me, after which I gave an overview of the major types of medical writing projects and work settings. For the discussion of the nature of the job, Amy focused on preparing peer to peer communications, while I focused on pharmaceutical regulatory writing. We employed an easy-going conversational style as we discussed key responsibilities and recommended skill sets for a medical writer and the importance of building a portfolio. One of the things we emphasized is that medical writing is different than writing about your own work as a scientist in that you need to focus on your target audience's needs. Additionally, we agreed that medical writers in both areas need to be collaborative as well as independent. The attendees were really engaged and asked great questions during and after the presentation, such was what is a typical document timeline and do you get an office or a cubicle as a writer.

The panel discussion was very fun and non-intimidating because it's exciting to talk about medical writing and the small audience was so interested. So next time you see a call to participate on a panel discussion about medical writing, I would suggest jumping on it. You'll be glad you did.

NOELLE H DEMAS, MS is an independent consultant providing regulatory writing services to pharmaceutical and medical device companies and contract research organizations. She began her career has a technical writer for medical devices and software in 1992, and transitioned to pharmaceutical writing in 1998 with full time positions in San Diego at Biogen Idec, Premier Research Group, SCIREX Corporation, and Alliance Pharmaceutical. She holds an MS in Technical Communication from the University of Colorado at Denver, as well as a BA in Biology and a Certificate in Technical Writing from California State University, Fullerton. She has been an active member of the American Medical Writers Association for several years serving in various volunteer roles including her recent role as the annual conference administrator for 2015. She can be reached via LinkedIn at https://www.linkedin.com/in/noelledemas

Marilyn Allison on Making Career Transitions

Susan Vintilla-Friedman, MWC

President, AMWA Pacific Southwest Chapter

On March 12, 2016 at Becton, Dickinson and Company (BD) in San Diego our chapter was delighted to present Marilyn Allison, PhD on the topic of Career Transitions. Marilyn herself began as an English professor before transitioning into technical writing and project management, and is now the Director of Learning and Development for BD. Her presentation described how to develop clear and realistic career goals, recognize and develop transferable skills, and maximize networking opportunities. Highlights of her talk included "connecting the dots" from previous work experiences to present yourself for new positions, and how to build new work experiences through learning new skills, volunteering, and being mentored. She explained that taking on a completely new role is one of the best ways to build new skills. Marilyn also emphasized the importance of developing emotional intelligence and self-awareness, and how to use feedback from interviews and work evaluations to develop your career. Since many of our chapter members have experience in academia, Marilyn also discussed some of the issues in transitioning to corporate, freelance, and nonprofit work.

Marilyn may expand this interactive presentation into a career transitions workshop in the future, and we will keep our chapter members informed of this possibility. We would like to thank Marilyn and BD again for providing an excellent presentation and venue for our members!

Event pictures by Donna Sincoe and Susan Vintilla-Friedman. Wrigley Field by Delventhal, https://flic.kr/p/6yxLDk; permissions: CC BY 2.0.

Chapter Upcoming Events Calendar

AMWA Pacific Southwest Chapter lunch (monthly) teleconference
Occurs First Friday of the month, 12-1 pm Pacific time
Dial in number: 706-913-1155
Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)

April 16,2016 – **AMWA Pacific Coast Conference**
Where: Park Central San Francisco, A Starwood Hotel, 50 Third Street, San Francisco, CA 94103. Visit http://amwancal.org/ for more information.

April 29, 2016 (tentative) – Webinar presentation by Thomas Purcell on **Project Management for Medical Writers**.

AUTHOR BIOSKETCHES

See pages 46 and 57 for articles by Rebecca Anderson and Dikran Toroser, respectively.

REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a Ph.D. in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.

DIKRAN TOROSER, PhD, CMPP, a member of the AMWA Pacific Southwest chapter, is a regular contributor to the *Postscripts* magazine since 2012. He developed the monthly AMAzing Style column which covers topics from the AMA Manual of Style, and has also written on publication-related topics in these pages. Dikran is currently a Senior Medical Writing Manager at Amgen Inc. in Thousand Oaks, California. He earned his PhD in Biochemistry from Newcastle University (UK), and did his post-doctoral training in biochemical genetics at the John Innes Center of the Cambridge Laboratory (Norwich, UK) and in molecular biology with the USDA. Prior to Amgen, Dikran was on the faculty (research) at the School of Pharmacy at the University of Southern California. He can be reached at dtoroser@amgen.com.

Zaha Hadid, the Creator of Seamless Flowing Architecture

Clockwise from top left: Heydar Aliyev Cultural Center, Baku, Azerbaijan; Innovation Tower, Hong Kong;Wangjing SOHO, Beijing; Dongdaemun Design Plaza & Park, Seoul; Bridge Pavilion, Zaragoza, Spain; (Center: Hungerburgbahn stations, Innsbruck, Austria); SOHO, Beijing; BMW Central Building, Leipzig, Germany. Zaha's portrait on bottom left.

Dame Zaha Hadid, a British architect, was best known for liberating building designs from the traditional geometrical constraints. Her projects used advanced construction and building material technologies to create seamlessly flowing structures creating new spacial patterns.

She was the first woman to be honored with Pritzker Architecture Prize (considered the Nobel Prize of Architecture) in 2004. She also received numerous other honors throughout her career, including Stirling Prize by Royal Institute of British Architects, being named “Artist for Peace” by UNESCO, Dame Commander of the British Empire, first woman to be awarded RIBA Gold Medal, and many others.

Born in Iraq and educated in Beirut and London, she was on the faculty or regularly taught at Harvard School of Design, University of Illinois at Chicago School of Architecture, Yale, HFBK Hamburg, University of Applied Arts Vienna, to name a few. She died last month (March 31st) in Miami at the age of 65, but her legacy lives on through her architectural creations and the firm she founded, Zaha Hadid Architects based in London.

SOURCES:

- Zaha Hadid Architects. http://www.zaha-hadid.com/
- Wikipedia: https://en.wikipedia.org/wiki/Zaha_Hadid
- List of works by Zaha Hadid: https://en.wikipedia.org/wiki/List_of_works_by_Zaha_Hadid
- Huffington Post: Tour some of Zaha Hadid's iconic buildings via Google Street View http://www.huffingtonpost.com/entry/zaha-hadid-architecture-photos-streetview_us_56fd7a2ce4b0a06d58053e00

—Editor